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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Andrew R. Marks and Steven O. Marx
U.S. Serial No. : 09/766,944
Filed : January 22, 2001
For : P27 PREVENTS CELLULAR MIGRATION

1185 Avenue of the Americas
New York, New York 10036
April 20, 2001

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants would like to direct the Examiner's attention to the following references which are listed on the attached Form PTO-1449 (**Exhibit 1**) and attached hereto as **Exhibits 2-12**:

Braun-Dullaeus, R. C., et al. (1997). Loss of p27kip1 and induction of Cdk1 in the rat carotid artery following balloon catheter injury. In vivo and in vitro influence of rapamycin. FASEB J 11, A153 (abstract) (**Exhibit 2**).

Braun-Dullaeus, R. C., Mann, M. J., Ziegler, A., von der Leyen, H. E., and Dzau, V. J. (1999). A novel role for the cyclin-dependent kinase inhibitor p27kip1 in angiotension II-stimulated vascular smooth muscle cell hypertrophy. J. Clin. Invest. 104, 815-823 (**Exhibit 3**).

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Cao, W., Mohacsi, P., Shorthouse, R., Pratt, R., and Morris, R. (1995). Effects of rapamycin on growth factor-stimulated vascular smooth muscle cell DNA synthesis: inhibition of basic fibroblast growth factor and platelet-derived growth factor action and antagonism of rapamycin by FK506. *Transplantation* 59, 390-395 (Exhibit 4).

Gallo, R., Padurean, A., Jayaraman, T., Marx, S. O., Roque, M., Adelman, S., Chesebro, J., Fallon, J., Fuster, V., Marks, A. R., and Badimon, J. J. (1999). Inhibition of intimal thickening after balloon angioplasty in porcine coronary arteries by targeting regulators of the cell cycle. *Circulation* 99, 2164-2170 (Exhibit 5).

Gregory, C., Huie, P., Billingham, M., and Morris, R. (1993). Rapamycin inhibits arterial intimal thickening caused by both alloimmune and mechanical injury. *Transplantation* 55, 1409-1418 (Exhibit 6).

Luo, Y., Marx, S. O., Kiyokawa, H., Koff, A., Massague, J., and Marks, A. R. (1996). Rapamycin resistance tied to defective regulation of p27kip1. *Mol. Cell. Biol.* 16, 6744-6751 (Exhibit 7).

Marx, S. O., Jayaraman, T., Go, L. O., and Marks, A. R. (1995). Rapamycin-FKBP inhibits cell cycle regulators of proliferation in vascular smooth muscle cells. *Circ. Res.* 76, 412-417 (Exhibit 8).

Poon, M., Marx, S. O., Gallo, R., Badimon, J. J., Taubman, M. B., and Marks, A. R. (1996). Rapamycin inhibits vascular smooth muscle cell migration. *J. Clin. Invest.* 98, 2277-2283 (Exhibit 9).

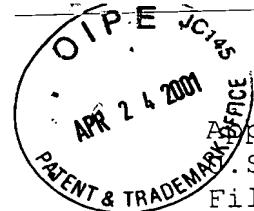
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Poston, R. S., Billingham, M., Hoyt, E. G., Pollard, J., Shorthouse, R., Morris, R. E., and Robbins, R. C. (1999). Rapamycin reverses chronic graft vascular disease in a novel cardiac allograft model. *Circulation* 100, 67-74 (Exhibit 10).

Sousa, J. E., Costa, M. A., Abizaid, A., Abizaid, A. S., Feres, F., Pinto, I.M.F. et al. (2000) Lack of neointimal proliferation after implantation of sirolimus-coated stents in human coronary arteries. A quantitative coronary angiography and three-dimensional intravascular ultrasound study. *Circulation* 102, r54-r57 (Exhibit 11).

Steeg, P. S., and Abrams, J. S. (1997). Cancer prognostics: Past, present and p27. *Nature Med.* 3, 152-154 (Exhibit 12).

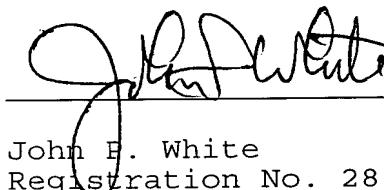
If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.



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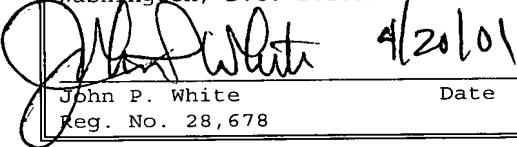
Applicants are submitting this Information Disclosure Statement under 37 C.F.R. §1.97(b)(1) within three months of the filing date of a national application. Accordingly, no fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if a fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
Assistant Commissioner for Patents,
Washington, D.C. 20231.


John P. White
Reg. No. 28,678

Date
4/20/01